

Prosecution Status

Applicants note with appreciation that prosecution in this case has been reopened following an appeal conference and that the finality of the Official Action mailed February 12, 2003, has been withdrawn. *See Official Action, Page 2.*

Applicants also note with appreciation that Applicants' amendments and remarks filed June 6, 2003, have been entered. *See Official Action, Page 2.*

Rejection Under 35 U.S.C. § 112, First Paragraph — Enablement

Claims 118-120 have been rejected under 35 U.S.C. § 112, First Paragraph, as purportedly not enabled. *See Official Action, Pages 2-3.* According to the Examiner, Claims 118-120 contain "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *See Official Action, Page 2.* This rejection is respectfully traversed.

"The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification **describe how to make and how to use the invention**. . . . The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art **how to both make and use the claimed invention.**"

M.P.E.P. § 2164 (emphasis added).

"The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: **is the experimentation needed to**

practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term 'undue experimentation,' it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation." *M.P.E.P.* § 2164.01 (emphasis added). "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." *Id.*

Keeping the foregoing mandates regarding enablement in mind, Applicants respectfully submit that Claims 118-120 are fully enabled. Recall, rejected Claims 118-120 are directed to, respectively: methods for inhibiting β-amyloid peptide synthesis and/or release in a mammalian subject thereby inhibiting onset of diseases mediated by β-amyloid peptide, methods for inhibiting β-amyloid peptide synthesis and/or release in a human subject thereby inhibiting onset of diseases mediated by β-amyloid peptide, and methods for treating a human subject with Alzheimer's Disease in order to inhibit further deterioration in the condition of said human subject, all of these methods comprising administering a pharmaceutical composition comprising a pharmaceutically-inert carrier and an effective amount of a compound or a mixture of compounds of formula IA. As such, Claims 118-120 require one to make one or more compounds of formula IA and then to use those compounds as directed in each method.

With respect to the first prong of the enablement analysis — the "how to make" inquiry — Applicants assert that one skilled in the chemical arts can readily rely upon the vast compound preparation data disclosed in the Specification to make the compounds

employed in the claimed methods. *See, e.g., Specification Pages 161-163 "Compound Preparation;" Pages 163-171 "Synthesis of Carboxylic Acid Starting materials;" Pages 171-203 "Preparation of Cyclic Amino Compounds;" and Pages 214-734 (setting forth, in detail, how to make many specific compounds).*

With respect to the second prong of the enablement analysis — the "how to use" inquiry — Applicants assert that one skilled in the chemical arts can readily rely upon the vast formulation and utility information disclosed in the Specification to use the compounds employed in the claimed methods. *See, e.g., Specification Pages 203-212 "Pharmaceutical Formulations" and Pages 212-214 "Utility."* Applicants also assert that one skilled in the chemical arts can readily rely upon the biological data disclosed in the Specification to use the compounds employed in the claimed methods. *See Specification Pages 735-740.*

Because one skilled in the chemical arts can readily both make and use the compounds employed in the claimed methods, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, enablement rejection against Claims 118-120.

The Examiner asserts that the "specification is not adequately enabling for the scope of the compounds embraced by the claims. . . . The instant scope is enormous, in the billions of compounds, and therefore one compound within its scope is not remotely representative of such a scope." *Official Action, Pages 2-3.* Applicants request clarification as to the meaning of "one compound." Moreover, Applicants respectfully assert that comments indicating nothing more than a concern over the breadth of disputed claims are of no relevance to a 35 U.S.C. § 112, First Paragraph, enablement inquiry. *See*

In re Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971). "As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for the enabling support." *Id.* "It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure **and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.** Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *Id.* at 223-224 (emphasis added).

Applicants respectfully request that the Examiner explain why he doubts the truth or accuracy of the statements made in the instant application coupled with acceptable evidence or reasoning which is inconsistent with statements made in the instant application. *See In re Barr*, 444 F.2d 588, 596 (C.C.P.A. 1971).

Provisos

The Examiner states that there "are provisos in the claims that exclude compounds embraced by the claims." *See Official Action, Page 3.* The Examiner has asked that "[i]f these provisos are present to avoid prior art, applicants are urgently requested to point out

these references to the examiner because of their importance in the examination of the claims." *See Official Action, Pages 3-4.*

Applicants request clarification. There is no outstanding rejection with respect to those provisos, and so it is unclear what Applicants' burden is with respect to those provisos. Applicants will provide the requested information in response to a proper rejection and it is established that Applicants must provide that information to make a fully-responsive reply.

Line of Demarcation

The Examiner has indicated that his search revealed that the elected compound is disclosed in several of Applicants' pending applications, citing WO 99/67221, WO 98/28268 and WO 2001/034571 (overlaps generically). *See Official Action, Page 5.* The Examiner has requested that the differences in scope between the instant application and applications corresponding to the foregoing international applications be provided. Applicants respectfully request clarification as to which "pending applications" the Examiner is referring and as to the foregoing comments, generally. Because no rejection has been made, it is not clear to Applicants under which statutory basis they are obligated to provide such information. In the absence of a proper rejection and statutory basis, Applicants are unable to assess whether they are obligated to reply, and if so, how to do so. Clarification is respectfully requested.

CONCLUSION

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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